CLAIMS

What is claimed is:

1. A method of treating a condition in a mammal, comprising:
   a. providing a recombinant adenovirus comprising a nucleotide sequence comprising an adenoviral inverted terminal repeat fusion sequence, a packaging signal, a transcriptional control region, and a nucleic acid encoding a therapeutic protein, wherein the remaining portion of said DNA molecule does not encode an adenoviral protein; and,
   b. administering said recombinant adenovirus to a mammal under conditions that result in the expression of the therapeutic protein at a level that provides a therapeutic effect in said mammal.
2. The method of claim 1 wherein said therapeutic protein is FVIII.
3. The method of claim 2 wherein said therapeutic protein is human FVIII.
4. The method of claim 1, wherein said therapeutic protein is expressed in the liver.
5. The method of claim 4 wherein said therapeutic protein is FVIII.
6. The method of claim 5 wherein said therapeutic protein is human FVIII.
7. The method of claim 7 wherein said recombinant adenovirus is FVIII.
8. The method of claim 8 wherein said therapeutic protein is human FVIII.
9. The method of claim 1, wherein the nucleic acid encoding the therapeutic protein is under the transcriptional control of a promoter.
10. The method of claim 1, wherein the nucleic acid encoding the therapeutic protein is under the transcriptional control of a tissue-specific promoter.
11. The method of claim 10, wherein said promoter is a liver-specific promoter.
12. The method of claim 11, wherein said promoter is an albumin promoter.
13. The method of claim 11, wherein said promoter is an alpha-fetoprotein promoter.
14. The method of claim 1 wherein the nucleotide sequence of said recombinant adenovirus further comprises an additional segment of cellular DNA.
15. The method of claim 14 wherein said additional segment of cellular DNA is a fragment of a gene.
16. The method of claim 15 wherein said additional segment of cellular DNA is a fragment of the albumin gene.

17. The method of claim 1, wherein said therapeutic protein is FVIII and the nucleic acid encoding FVIII is under the transcriptional control of a promoter.

18. The method of claim 1, wherein said therapeutic protein is FVIII and the nucleic acid encoding FVIII is under the transcriptional control of a tissue-specific promoter.

19. The method of claim 18, wherein said therapeutic protein is FVIII and the nucleic acid encoding FVIII is under the transcriptional control of a liver-specific promoter.

20. The method of claim 19, wherein said therapeutic protein is FVIII and the nucleic acid encoding FVIII is under the transcriptional control of an albumin promoter.

21. The method of claim 19, wherein said therapeutic protein is FVIII and the nucleic acid encoding FVIII is under the transcriptional control of an alpha-fetoprotein promoter.

22. The method of claim 17, wherein said therapeutic protein is FVIII, the nucleic acid encoding FVIII is under the transcriptional control of a promoter, and the nucleotide sequence of the recombinant adenovirus comprises an additional segment of cellular DNA.

23. The method of claim 22, wherein said therapeutic protein is FVIII, the nucleic acid encoding FVIII is under the transcriptional control of a tissue-specific promoter, and the nucleotide sequence of the recombinant adenovirus comprises an additional segment of cellular DNA.

24. The method of claim 23, wherein said therapeutic protein is FVIII, the nucleic acid encoding FVIII is under the transcriptional control of a liver-specific promoter, and the nucleotide sequence of the recombinant adenovirus comprises an additional segment of cellular DNA.

25. The method of claim 24, wherein said therapeutic protein is FVIII, the nucleic acid encoding FVIII is under the transcriptional control of an albumin promoter, and the nucleotide sequence of the recombinant adenovirus comprises an additional segment of cellular DNA.

26. The method of claim 24, wherein said therapeutic protein is FVIII, the nucleic acid encoding FVIII is under the transcriptional control of an alpha-fetoprotein

promoter, and the nucleotide sequence of the recombinant adenovirus comprises an additional segment of cellular DNA.

27. The method selected from the group consisting of the method of claim 22, 23, 24, 25, and 26 wherein said additional segment of cellular DNA is a fragment of the albumin gene.

28. The method of claim 1, wherein said recombinant adenovirus is administered by a route selected from the group consisting of oral, parenteral, inhalation, rectal, topical, intravenous, intrarterial, intrapleural, nasal, intrathecaly, and direct intaorgan injection.

29. The method of claim 17, wherein said recombinant adenovirus is administered by a route selected from the group consisting of oral, parenteral, inhalation, rectal, topical, intravenous, intrarterial, intrapleural, nasal, intrathecaly, and direct intaorgan injection.